

Claim 18, lines 1 to 2, delete "recombinant DNA molecule" and insert therefor --nucleic acid--, and line 2, delete "13", and insert therefor --7--.

#### REMARKS

Applicants have cancelled claim 13 and amended claims 7, 14, and 18. Cancellation of claim 13 is not in acquiescence to any outstanding rejections, and applicants reserve the right to pursue the subject matter of the cancelled claim in a continuing application.

The Examiner rejected claims 7, 13, 14, 18, and 23 under 35 U.S.C. § 112, first paragraph, "as the disclosure is enabling only for claims limited to DNA encoding the TNF-BP described as R<sup>2</sup>-Asp-Ser-Val-...." Office Action at page 2, lines 7-9.

First, the Examiner notes that claim 7 is directed to DNA "that hybridize[s] to the DNA encoding TNF-BP identified in claim 2 and encoding a protein that can bind to TNF." Id. at lines 10-12. The Examiner contends that such DNA "is beyond the scope of the disclosed Invention because there is no teaching in the specification what part of the TNF-BP is responsible for binding to TNF." Id. at lines 12-14.

The Examiner further contends that "[i]t is not predictable what part of the TNF-BP binds to TNF because no structure/function studies have been done such that one of ordinary skill in the art could know that part of the TNF-BP encoded by the DNA of Claim 2 [that] will retain TNF binding properties." Id. at lines 14-17. Considering only the alleged lack of guidance in the specification

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concerning what part of the molecule is responsible for binding and the alleged unpredictability of that factor, the Examiner concludes that "it would require undue experimentation for one of ordinary skill in the art to determine that part of TNF-BP encoded by the DNA of Claim 2 that is responsible for the TNF binding."

Id. at lines 17-19. For the following reasons applicants traverse this rejection, since the Examiner has failed to establish a *prima facie* case of nonenablement.

The Examiner focuses solely on an alleged lack of predictability and the alleged failure of the specification to show in advance what part of the TNF-BP is responsible for binding to TNF. The Examiner fails to consider the routine screening for determining whether TNF-BP encoded by such hybridizing sequences binds to TNF. The Examiner also fails to consider the high level of skill in this art. Applicants submit that the routine screening that one of skill in the art would undertake would not rise to the level of undue experimentation. It would merely require time.

The Examiner cites no authority that would support an enablement rejection based solely on a specification's failure to provide predictable results for all embodiments encompassed by the claims. In fact, the courts have repeatedly held that experimentation is permitted under 35 U.S.C. § 112, first paragraph, even in an unpredictable field. In re Angstadt, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976) (The court stated that to require predictability in advance is contrary to the basic policy of the Patent Act).

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The burden is on the Examiner to establish a *prima facie* case that undue experimentation would be required to make and use the claimed invention. Id. Here the Examiner has not considered the routine screening that one skilled in the art could carry out. The Examiner concludes that undue experimentation would be required, but provides no evidence concerning the type of experimentation involved or any particular difficulties one skilled in the art would encounter in screening molecules encoded by the claimed DNA for their ability to bind to TNF.

Unpredictability in advance, however, does not establish undue experimentation, since routine screening can be employed to test for binding activity of molecules encoded by the claimed DNA. DNA that encodes molecules that bind to TNF are within the claims, and those that do not encode such molecules are not covered by the claims. Even if not predictable in advance, such routine screening renders the present claims enabled in view of the present specification.

Applicants also point out that the specification does provide guidance for obtaining DNA sequences encompassed by claim 7. For example, see the specification at page 14, first full paragraph, through page 18, last full paragraph (in particular, see page 18, first full paragraph).

Accordingly, applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner also rejected claims 13, 14, 18, and 23 under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which the applicant regards as the invention." Office Action at page 3, lines 17-19. This rejection is based on the language of claim 13. (Claims 14, 18, and 23 all ultimately depend from claim 13.)

Applicants disagree that claim 13 requires further features for one skilled in the art to understand what is encompassed by it. Solely to expedite prosecution and not acquiescing in the rejection, however, applicants have cancelled claim 13. Also, claims 14, 18, and 23 now depend from claim 7. Accordingly, this rejection is moot.

The Examiner also rejected claims 3-5 under 35 U.S.C. § 112, fourth paragraph, "as being of improper dependent form for failing to further limit the subject matter of a previous claim." Office Action at the paragraph bridging pages 3 and 4. The Examiner contends that "[c]laims 3-5 depend from Claim 2 wherein the  $R^2$  is optionally present or absent. When  $R^2$  is absent, the  $R^2$  of Claims 3-5 do not further limit the sequence depicted in Claim 2." Id.

Applicants respectfully traverse this rejection. Claim 2 is a generic claim that encompasses embodiments that include  $R^2$  or embodiments that do not include  $R^2$ . Claims 3-5 are species of the genus of claim 2 that all include  $R^2$ . Accordingly, claims 3-5 further limit the genus of claim 2 by requiring specific  $R^2$  groups. (By definition, claims 3-5 require that  $R^2$  be present.)

Accordingly, applicants respectfully request reconsideration and withdrawal of this section 112, fourth paragraph, rejection.

The Examiner also rejected claims 2-7, 9-14, 17, 18, 22, and 23 under 35 U.S.C. § 103 "as being unpatentable over Olsson et al.

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(March, 1989) [Olsson] in view of Leung et al. (December, 1987) [Leung]." Office Action at page 4, lines 24-26. The Examiner contends that Olsson discussed isolating TNF-BP from urine and showed a particular N-terminal amino acid sequence of TNF-BP. Id. at lines 26-31. The Examiner admits that Olsson "do[es] not teach the cDNA encoding the TNF-BP or the signal sequence for its secretion." Id. at page 5, lines 2-3.

The Examiner then provides a detailed discussion concerning obtaining DNA encoding growth hormone receptor and the relationship between growth hormone receptor and growth hormone binding protein, which is discussed in Leung. Id. at page 5, line 4, through page 6, line 5. The Examiner concludes that "[i]t would have been obvious to a person of ordinary skill in the art to acquire the cDNA encoding the TNF-BP described by Olsson et al. using the method of Leung et al. with the obvious modifications of the method directed to the particulars of the TNF-BP . . . ." Id. at page 6, lines 6-9. In summary, the Examiner applies the methods of Leung for isolating DNA different than that presently claimed to the partially sequenced molecule of Olsson. Applicants respectfully traverse this rejection since it is at odds with legal precedent that is directly on point.

Specifically, in In re Deuel, the Federal Circuit held that knowledge of a protein, even if it is partially sequenced, does not render obvious the DNA that encodes that protein, even if methods had been known to isolate DNA using amino acid sequence information. In re Deuel, 34 U.S.P.Q.2d 1210, 1215-16 (Fed. Cir. 1995). In that case, the prior art included a partial amino acid

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sequence and general cloning methods that allegedly could have been used to obtain the claimed DNA using the partial amino acid sequence information.

The Federal Circuit stated that "[t]he PTO's focus on known methods of potentially isolating the claimed DNA molecule is also misplaced because the claims at issue define compounds, not methods." Id. at 1215. The Court also stated that "a conceived method of preparing some undefined DNA does not define it with the precision necessary to render it obvious over the protein it encodes." Id. at 1216. Additionally, the Court held that a claim encompassing degenerate DNA sequences encoding a particular protein would not have been obvious in view of a disclosure of a partial amino acid sequence of that protein and a disclosure of methods of using partial amino acid sequence information to obtain other DNA. Id.

In summary, the Court held that unless the structure of the DNA was disclosed, proposed methods of obtaining the DNA would not render obvious the claimed DNA. Accordingly, applicants respectfully request reconsideration and withdrawal of the section 103 rejection of the claims.

For these reasons, applicants submit that all of the pending and presently considered claims are in condition for allowance. Thus, applicants respectfully request issuance of a Notice of Allowance.

If there are any fees due in connection with the filing of Preliminary Amendment, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of

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time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Dated: November 22, 1995

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